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RECENT ADVANCES IN SURGERY

36

Irving Taylor
Colin D Johnson

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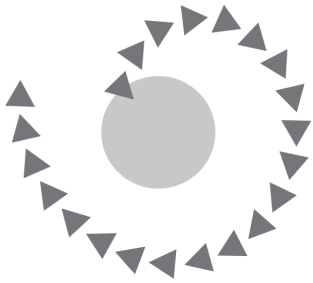

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Chapter

2 Local Anaesthetics in Surgical Practice

Lisa Sharp, James French

INTRODUCTION

As surgical practise advances, we challenge the anaesthetist further to provide new techniques that achieve excellent analgesia for patients without systemic side-effects or dense motor blockade from regional techniques, thus enabling early ambulation.

In the fast changing world of medicine, emphasis is shifting towards day-case, short-stay and ambulatory care provision. Enhanced recovery programmes are becoming increasingly important and local anaesthesia has a fundamental role in achieving early discharge of patients.

The National Health Service (NHS) Institute for Innovation and Improvement[1] champions enhanced recovery programmes as improving patient outcomes, speeding recovery, benefiting patients and staff by making patients active participants in their recovery process and ensuring care is evidence based and delivered at the appropriate time.

The four elements of enhanced recovery programmes:

1. Preoperative assessment, planning and preparation before admission
2. Reducing the physical stress of the operation
3. A structured approach to immediate postoperative and perioperative management, including pain relief
4. Early mobilisation.

Effective analgesia can assist in achieving all except the first of these elements.

Nielsen[2] reviewed over 15,000 consecutive ambulatory surgical procedures. Pain accounted for 12% of unanticipated hospital admissions, 60% of these were orthopaedic patients. The scope of orthopaedic procedures performed in ambulatory settings is restricted by inadequate analgesia. Effective analgesia provided by catheters, drugs with prolonged duration of action and practises which can be continued into the postdischarge

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period will be the cornerstone of expanding ambulatory care, subsequently reducing length of stay (LOS), postoperative nausea and vomiting (PONV) and indirectly reducing healthcare expenditure by cost containment.

PROSPECT[3] is a clinical tool for procedure-specific postoperative pain management in common surgical procedures; abdominal hysterectomy, colonic resection, laparoscopic cholecystectomy, total hip arthroplasty, total knee arthroplasty, herniorrhapy, haemorrhoid surgery, noncosmetic breast surgery and thoracotomy. The recommendations are produced by expert working groups based on current published evidence and are structured into pre-, intra- and postoperative guidelines. Regional and local anaesthesia feature heavily in the guidelines illustrating a need for clinicians to be knowledgeable of these strategies.

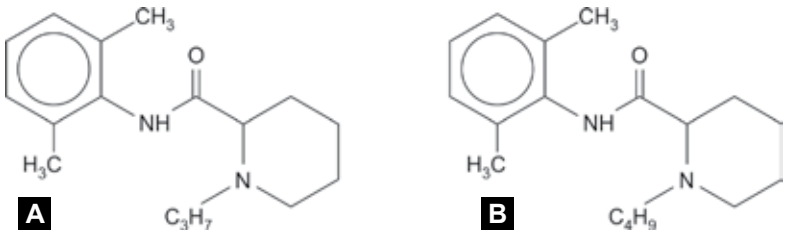
PHARMACOLOGICAL ADVANCES

In 1979, Albright published an editorial detailing six cases of ventricular arrhythmias, without prodromal symptoms and simultaneous in onset with convulsions,[4] in response the Food and Drug Administration (FDA) banned use of 0.75% bupivacaine for obstetrics. The search commenced for a new drug and a "test dose" to reliably identify intravascular injection.

Ester local anaesthetics (LAs) cause more allergic reactions and so predominant interest was in amino-amide LA. Significant differences between the toxicity of the S(-) and R(+) enantiomers had previously been demonstrated[5] so development of a new long-acting LA concentrated on producing a pure S(-) enantiomer. The pipecoloxylidides, ropivacaine and levobupivacaine were the result (Figs 2.1A and B). Both have been shown in clinical trials to exhibit less cardiotoxicity than racemic bupivacaine.[6]

Ropivacaine

The S-isomer of 1-propyl-2′,6′-pipecoloxylidide is produced commercially as a 99.5% pure enantiomer. First registered for clinical use in 1996, ropivacaine is now commonly used for wound infiltration, peripheral nerve blocks and epidural use.



Figs 2.1A and B: (A) Ropivacaine; (B) Levobupivacaine

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It exhibits onset of action similar to bupivacaine due to the identical pKa but dissociates from sodium channels more rapidly than racemic bupivacaine.[7] The lower lipid solubility of ropivacaine is presumed to impair penetration of myelin sheaths resulting in greater differential block of motor and sensory fibres.

Epinephrine has been found to have little clinical effect on analgesic activity or systemic concentrations of ropivacaine, hence there is no combined formulation.[8]

Ropivacaine has been shown not to have any antimicrobial activity unlike bupivacaine.[9] Evidence supports the R-enantiomers of racemic bupivacaine to be more bacteriostatic.[10]

Levobupivacaine

The S-enantiopure isomer of bupivacaine only came into clinical use this millennium. A review of levobupivacaine has shown it to have an enhanced safety profile with a greater margin of safety; an increased dose of levobupivacaine is required to produce both excitatory central nervous system (CNS) effects and myocardial toxicity.[11] LAs concomitantly exert vasoactive effect on blood vessels. Vasoconstriction may provide additional safety benefits by limiting systemic uptake of local anaesthetics; levobupivacaine is consistently associated with less vasodilatation at site of injection.[12]

There is conflicting evidence surrounding superiority of ropivacaine over levobupivacaine. 25–40% greater dosage of ropivacaine is required for equipotency; this may be related to the differential motor/sensory blockade and increased doses required to reach toxicity threshold with differences related to total mass of drug and potency rather than pharmacological effect. Interpretation is confused by use of racemic bupivacaine as the active comparator in most studies of ropivacaine and levobupivacaine rather than one another.

Short-Acting Local Anaesthetics for Spinal Anaesthesia

Ambulatory surgery has created a need for short-acting spinal anaesthesia. Popularity of intrathecal lignocaine is declining as a result of reports of transient neurological symptoms (TNS). Rather than looking for new drugs, there has been a renaissance of old drugs.

Heavy Prilocaine

Prilocaine is an amide LA with duration of action similar to lignocaine (70–90 minutes). The hyperbaric preparation was withdrawn in the late 1970s following unresolved issues of stability and case reports of inadequate

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blockade.[13] Redevelopment of 2% heavy prilocaine hydrochloride with prolonged shelf-life (5 years at ambient temperature) has invoked renewed interest, supported by studies showing a significantly lower incidence of TNS when compared to lignocaine.[14]

2-Chloroprocaine

2-Chloroprocaine is an ester LA, used for epidural and peripheral nerve blockade. Its popularity declined in the 1980s after reports of prolonged sensory/motor deficits following accidental subarachnoid injection and it was never released for use in the UK. Its pharmacological profile; rapid onset, short-acting (30–60 minutes) and low systemic toxicity make it perfect for the purpose of ambulatory surgery. 2-Chloroprocaine use is increasing in Europe. A recent review[15] concluded preservative-free 2-chloroprocaine to be a reliable LA for short procedures, with a decreased time to ambulation and discharge when used intrathecally compared to articaine[16] and lignocaine[17] for day-case knee arthroscopic[16] and transurethral resection of the prostate (TURP)[17] surgery respectively. There were five possible cases of TNS in > 4,000 patients, and one description of a regressive incomplete cauda equina syndrome, a more favourable risk than lignocaine.

Lipid Emulsion for Toxicity

Despite the improved safety profile of the S-enantiomers, they do not completely negate the risk of local anaesthetic systemic toxicity (LAST) resulting from inadvertent intravenous injection or LA overdose. However should LAST occur and refractory cardiac arrest develop, administration of lipid emulsions as part of resuscitation have been successful.

In 1998, Weinberg et al.[18] showed a lipid infusion (soyabean oil emulsion used for TPN) could prevent/improve resuscitation from cardiac toxicity secondary to bupivacaine overdose in anaesthetised rats. This was confirmed in dogs.[19] The first successful case report of resuscitation in a human was published in 2006.[20]

There are several theories about how lipid emulsions function, the most popular being the "lipid sink"—infused lipid emulsion binds the LA in sufficient quantities to remove it from target tissues, reversing toxicity. This theory is supported by evidence that it has effect in both cardiac and neurological toxicity, despite brain tissue itself not metabolising fatty acids to any appreciable degree.[21] There are reports of successful resuscitation in other drug overdoses (tricyclic antidepressants, beta-blockers, calcium channel blockers) where there is the lack of any common mechanisms, the only shared factor being lipid solubility (octanol: water partition coefficient > 2).[21] Other theories include lipid offsetting inhibition of fatty acid metabolism caused by bupivacaine, supported by studies in isolated rat

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hearts where lipid concentrations too low to reduce bupivacaine content reversed bupivacaine-induced cardiac functional impairment[22] and modulation of cardiac sodium channels by free fatty acids.[23] Several factors may interact.

Randomised controlled trials (RCTs) studying lipid infusion would never gain ethical approval. Case reports remain our only evidence base. There is now a global on-line registry: www.lipidrescue.org.[24] It collates and analyses clinical data on attempted lipid-rescue resuscitation to create an accurate picture of patient outcomes whilst avoiding publication bias. It disseminates information and publishes protocols for administration in 18 different languages. The Association of Anaesthetists of Great Britain and Ireland (AAGBI) administration protocol is shown (Fig. 2.2). On balance the evidence in favour of lipid emulsion in this situation appears overwhelming. To date, there are no reported serious clinical consequences from lipid rescue.[24] Despite severe hyperlipidaemia and development of hyperamylasaemia in two patients, neither experienced symptomatic pancreatitis. However, theoretical concerns mandate continued assessment of patients postlipid rescue. Hyperlipidaemia can interfere with standard laboratory tests.

A new debate begins—the optimal lipid formulation—whether it should remain solely long chain triglycerides (LCTs) or a combination with medium-chain triglycerides (MCTs). Currently available evidence is contradictory.[25,26] Ruan's study[25] may be more representative of outcome as it uses human serum rather than buffer solution or animal models.

THE FUTURE

Enhanced recovery has created requirement for drugs which provide shorter-duration surgical anaesthesia (intrathecal prilocaine and 2-chloroprocaine). However, effective programmes require ongoing effective postoperative analgesia. Utilisation of systemic and intrathecal analgesics, predominantly opioids, catheters and elastomeric pumps provide a method for prolonging analgesia but novel drug delivery systems may be the future.

Pharmacological and technological advances have enabled encapsulation of drugs to act as reservoirs allowing deposit of large amounts of drug which release slowly to produce prolonged effective analgesia, without the inherent risks of toxicity.

Several encapsulating systems are undergoing research and development; liposomes, lipospheres, polylactic microspheres. Essential prerequisites for these agents are provision of predictable, controlled drug release which is reliable and achieves therapeutic concentration without risk of "burst release", a phenomenon where drug is rapidly released risking systemic toxicity.

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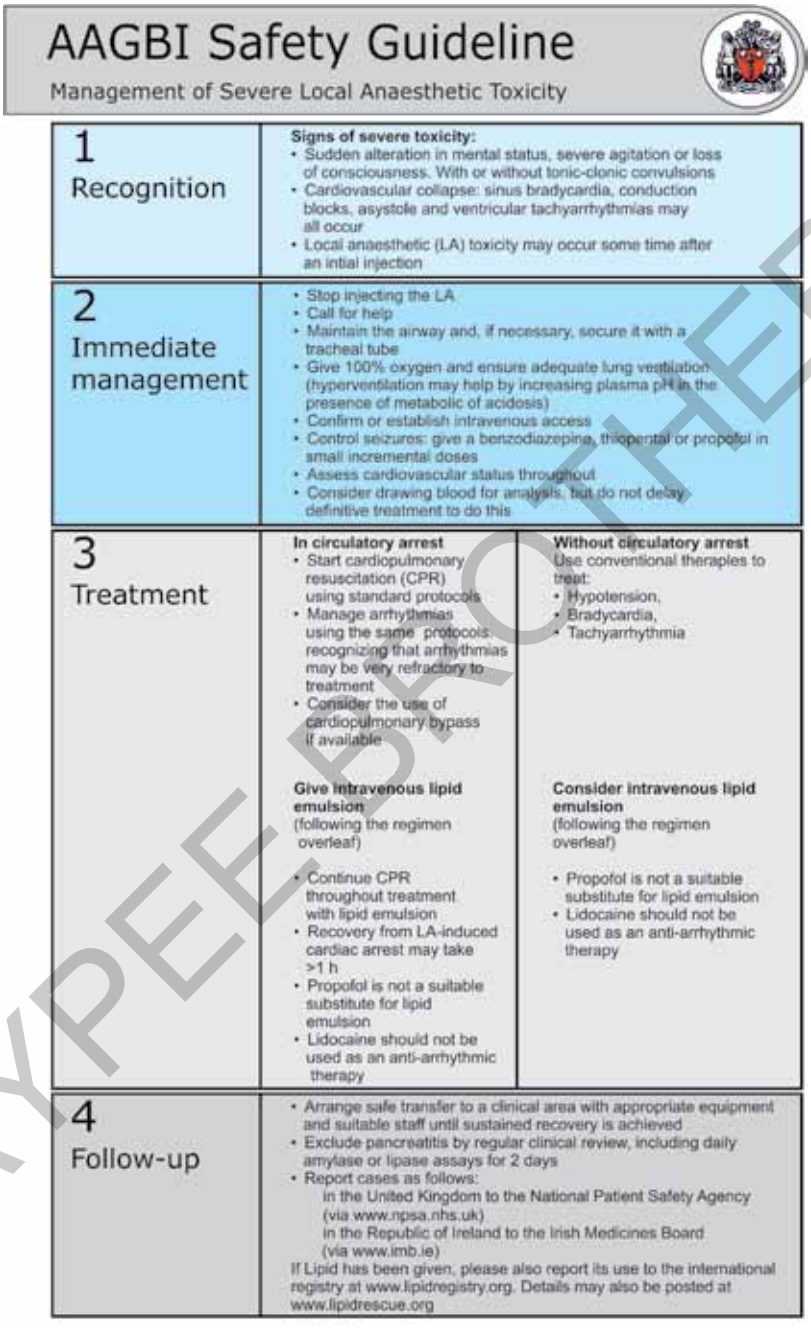

AAGBI Safety Guideline

Management of Severe Local Anaesthetic Toxicity

1 Recognition

Signs of severe toxicity:

- Sudden alteration in mental status, severe agitation or loss of consciousness. With or without tonic-clonic convulsions
- Cardiovascular collapse: sinus bradycardia, conduction blocks, asystole and ventricular tachyarrhythmias may all occur
- Local anaesthetic (LA) toxicity may occur some time after an intial injection

2 Immediate management

- Stop injecting the LA
- Call for help
- Maintain the airway and, if necessary, secure it with a tracheal tube
- Give 100% oxygen and ensure adequate lung ventilation (hyperventilation may help by increasing plasma pH in the presence of metabolic of acidosis)
- Confirm or establish intravenous access
- Control seizures: give a benzodiazepine, thiopental or propofol in small incremental doses
- Assess cardiovascular status throughout
- Consider drawing blood for analysis, but do not delay definitive treatment to do this

3 Treatment

In circulatory arrest

- Start cardiopulmonary resuscitation (CPR) using standard protocols
- Manage arrhythmias using the same protocols recognizing that arrhythmias may be very refractory to treatment
- Consider the use of cardiopulmonary bypass if available

Give intravenous lipid emulsion
(following the regimen overleaf)

- Continue CPR throughout treatment with lipid emulsion
- Recovery from LA-induced cardiac arrest may take >1 h
- Propofol is not a suitable substitute for lipid emulsion
- Lidocaine should not be used as an anti-arrhythmic therapy

Without circulatory arrest
Use conventional therapies to treat:

- Hypotension,
- Bradycardia,
- Tachyarrhythmia

Consider intravenous lipid emulsion
(following the regimen overleaf)

- Propofol is not a suitable substitute for lipid emulsion
- Lidocaine should not be used as an anti-arrhythmic therapy

4 Follow-up

- Arrange safe transfer to a clinical area with appropriate equipment and suitable staff until sustained recovery is achieved
- Exclude pancreatitis by regular clinical review, including daily amylase or lipase assays for 2 days
- Report cases as follows:
  in the United Kingdom to the National Patient Safety Agency (via www.npsa.nhs.uk)
  in the Republic of Ireland to the Irish Medicines Board (via www.imb.ie)

If Lipid has been given, please also report its use to the international registry at www.lipidregistry.org. Details may also be posted at www.lipidrescue.org

You nearest bag of Lipid Emulsion is kept .....

The guideline is not standard of medical care. The ultimate judgement with regard to a particular clinical procedure or treatment plan must be made by the clinician in the light of the clinical data presented and the diagnostic and treatment options available.

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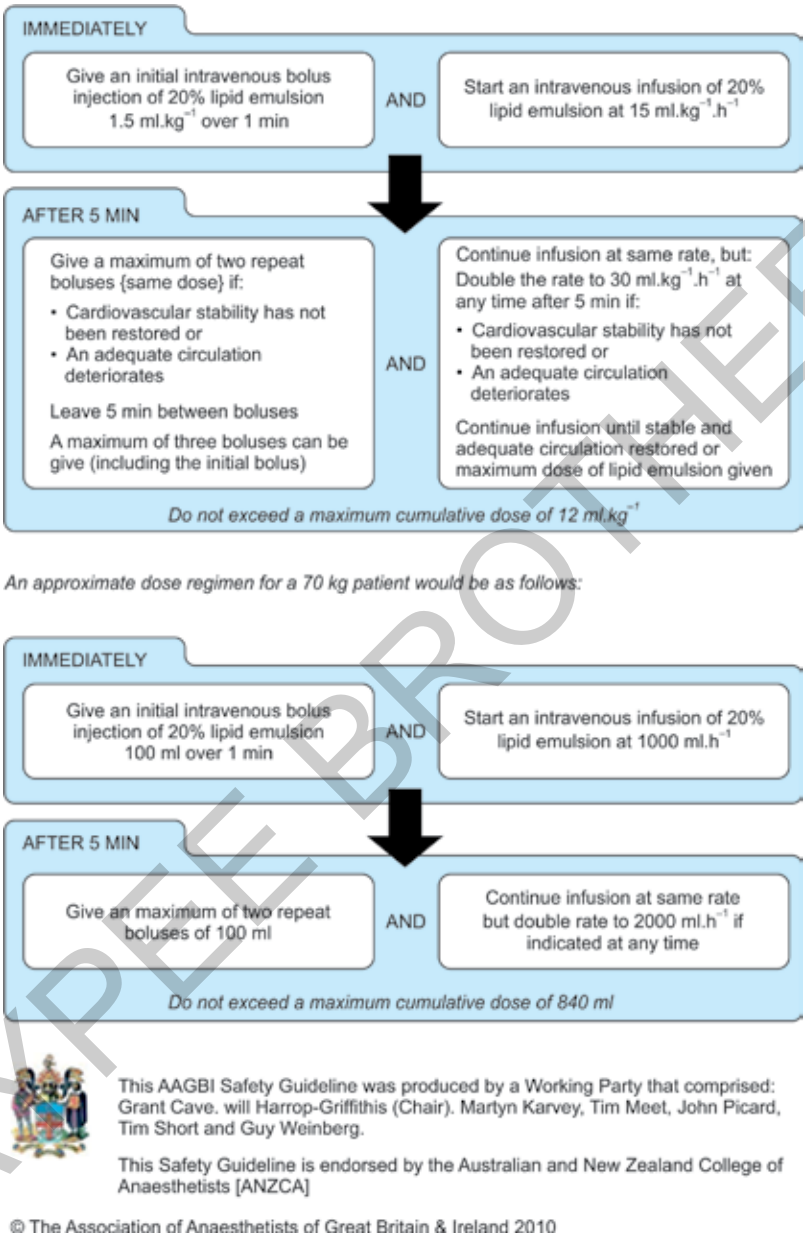

Fig. 2.2: AAGBI Safety Guideline: Management of severe local anaesthetic toxicity
Source: Reproduced with kind permission from AAGBI

Liposomes

EXPAREL®, liposomal bupivacaine is the only LA encapsulation to have achieved FDA approval. It uses Depofoam® as a delivery platform, which has been used successfully in other commercial products (cytarabine

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liposome injection, extended-release morphine).[27] Commercial launch was announced in April 2012. EXPAREL® is a microscopic (24–31 μm diameter) spherical liposome which is multivesicular, composed of numerous non-concentric internal aqueous chambers containing bupivacaine; each chamber is separated from the adjacent chamber by lipid membranes. They contain the novel lipid excipient 1, 2-dierucoylphosphatidylcholine (DEPC).[28]

There have been two multicentre, randomized, double-blind, parallel-group trials showing benefit of EXPAREL® as postoperative analgesia for haemorrhoidectomy and bunionectomy,[28] with reduced cumulative pain scores for up to 72 hours and 24 hours respectively. However these trials were placebo-controlled. The only active-comparator trial with bupivacaine in soft tissue surgery (SIMPLE C-312)[28] showed no statistically significant superiority for EXPAREL® as measured by area under curve of pain scores up to 96 hours postoperatively.

Currently, EXPAREL® is licensed for administration into the surgical site to produce postsurgical analgesia. It has not been evaluated for, and therefore is not recommended for under 18 years old, epidural, intrathecal, regional nerve block, intravascular or intra-articular use. There is current recruitment into trials considering additional indications. It is contraindicated in paracervical block.[29]

Administration of non-bupivacaine LAs locally is contraindicated because of their potential to cause burst release, and no other bupivacaine formulations should be administered for 96 hours due to toxicity risk.[29]

In efficacy and safety studies, the most common adverse events were nausea, constipation and dizziness. It exhibits favourable cardiovascular toxicity profile with maximum plasma concentration of 34,000 ng/mL reported during the EXPAREL® clinical study programme with no discernible adverse events or clinical sequelae.[29]

Microspheres

Microspheres are larger than liposomes, constructed of biodegradable polymers synthesized from polylactide acid polymer (PLA). Drug diffuses through the matrix slowing release. The release profiles of microspheres were dependent on the polymer, molecular weight and drug binding.[30] Currently published clinical trials for microspheres are very limited.

Implant

At surgery, nerve exposure enables implantation of modified release matrices. These may enable larger dose deposition than injectable forms. Xybrex®, a hand mouldable, absorbable delivery system providing slow-release of

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high-dose lignocaine has been shown in animal studies to provide effective analgesia for several days.[31]

Key Points

- No test dose for exclusion of intravascular placement is reliable, therefore incremental injection of 4–5 mL with sufficient pause between boluses is essential
- S(-) enantiomers of LA are less cardiotoxic and exhibit more intrinsic vasoconstriction than R enantiomers and racemic preparations
- Prilocaine and 2-chloroprocaine produce short-acting spinal anaesthesia for day-case ambulatory surgery
- Lipid emulsion is effective in preventing and assisting resuscitation in LA toxicity.

DELIVERY

Local infiltration is simple, inexpensive and does not require complex equipment. It is usually performed by the operating surgeon. There is broad but contradictory evidence related to its use. When considering local infiltration, evidence suggests it should be preincisional with meticulous detail to operative field and tissue planes involved. Dexamethasone, adrenaline, clonidine, opioids and ketorolac are adjuvants used with LA.

REGIONAL ANAESTHESIA

Ultrasonography

The use of regional anaesthesia (RA) to provide field blocks for surgical procedures and postoperative analgesia has increased exponentially over the last 15 years. Patients are experiencing better analgesia and fewer side-effects from systemic analgesics.

The revolution in performance of RA is predominantly a result of advances in ultrasound technology. It is beyond the scope of this chapter to give a detailed description of the advances in ultrasound technology and the numerous ultrasonographic nerve block techniques but the large numbers of publications support a move towards it becoming the recognised gold-standard for RA. 2-D ultrasonography is becoming commonplace in anaesthetic departments for block placement. 3-D and 4-D (real time 3-D) are undergoing assessment.

There is growing acknowledgement that direct visualisation of the needle tip ensures greater safety by preventing nerve damage from needle injury and inadvertent intravascular or intraneural injection; visualisation of the spread of the LA deposited around the desired nerve/plexus brings greater success, allows use of lower doses, reduced risk of toxicity and enhanced recovery. The overall result being faster onset blocks, better quality anaesthesia and analgesia, improved recovery and hence improved patient satisfaction.

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These factors alone can result in earlier discharge and greater throughput on a surgical list when combined with effective list management.

Technological developments have resulted in more user-friendly, smaller, portable ultrasound machines with better image resolution at lower cost. Needle development continues to search for a needle with even better echogenicity at all depths. For these techniques to become gold-standard and provide effective, safe patient care it is important we invest in equipment and more importantly training of the anaesthetist in ultrasound-guided RA.

Catheters and Elastomeric Pumps

To assist early ambulation and rehabilitation, analgesia needs to be extended into the postoperative period beyond that provided by a bolus dose of LA. Catheters inserted either under ultrasound guidance or directly by the surgeon intraoperatively offer a solution with direct visualisation of the proximity to the target nerve visualised. The development of elastomeric infusion pumps (Fig. 2.3) has reduced the need for patients with catheters to be attached to cumbersome infusion devices.

Local anaesthetic is delivered via a catheter attached to an elastomeric "balloon" which consistently deflates and gently pushes through LA solution. These devices are available in a variety of volumes with differing flow rates. Some have the capacity for administration of patient-controlled boluses. Development of multi-holed catheters allows greater spread of LA.

A plethora of catheter designs are emerging onto the market: single-holed, multi-holed (with holes over up to 25 cm), holes spiralling around the catheter giving 360° spread and some impregnated with silver for antimicrobial properties.[32]

A quantitative and qualitative systematic review of RCTs[33] supported efficacy of continuous wound catheters across a range of surgical specialties and procedures with variable dosing regimens and differing tissue layer

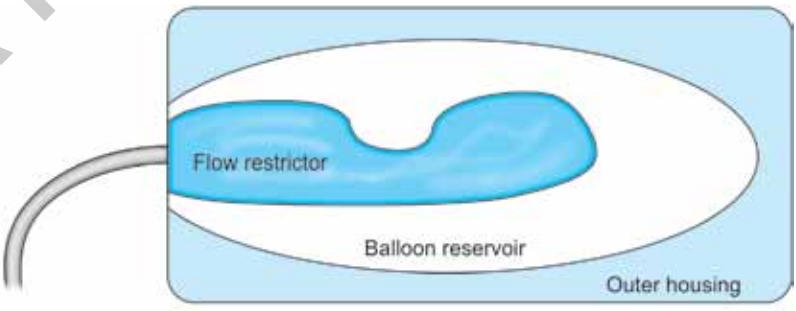

Fig. 2.3: Schematic diagram of an elastomeric pump

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situation showing improved analgesia, reduced PONV, opioid-use and LOS and greater patient satisfaction. Whilst they may not achieve the standard of analgesia of epidural and peripheral nerve blocks they are technically simpler and an effective alternative where such procedures are contraindicated. A white paper using such devices as a case study for health economics evaluation found them to be cost-effective and produce greater patient satisfaction.[34]

LOCAL ANAESTHETIC FOR LAPAROSCOPIC SURGERY

Provision of adequate analgesia for laparoscopic cholecystectomy in the ambulatory setting has always been challenging. Systematic reviews and meta-analyses[35,36] provide limited support for intraperitoneal instillation of LA but study designs and results showed considerable heterogeneity.

Nebulized LA should provide more uniform LA distribution intraperitoneally. When compared to non-nebulised intraperitoneal LA instillation[37] and placebo[38] shoulder tip pain and duration to unassisted walking postoperatively are reduced. Compared to placebo, morphine consumption is reduced however, there is a higher incidence PONV. These studies used a commercially available microvibration-based nebulisation device Aeroneb Pro®.

Key Points

- Local infiltration: Simple and cheap, meticulous detail to tissue planes and operative field mandatory
- Evaluation of new techniques should use current gold-standard as active comparator, as opposed to placebo
- Ultrasound guidance improves block success, allows lower doses and reduces risks nerve injury.

SUMMARY

Over the last decade, we have seen ever changing uses of LA. Regional blocks are no longer sited blindly by anaesthetists using painful stimulation of nerves, guided by their anatomic knowledge (as determined by textbooks, paying little attention to individual anatomical variation), with the reliance on a negative aspiration to determine that an intravascular injection is not about to occur and that if such an accidental injection does occur that they will be committed to prolonged resuscitation should the patient experience cardiovascular side-effects of toxicity. The nerves/plexus and needle are now visualised with ultrasound guidance and LA deployed in real time. Doppler application to the structures visualised improves determination of vessels.

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Drugs are produced as single enantiomers such that their tendency to toxicity is reduced and their toxicity profile improved. The discovery of lipid emulsion's ability to treat toxicity has improved treatment and survival from any such incident. The introduction of elastomeric pumps and a variety of catheter designs has allowed early discharge of patients with ongoing field blocks and wound infiltration.

Not only have these advances assisted the anaesthetist in their ability to provide anaesthesia for surgery and analgesia for postoperative pain, they have benefitted surgeons and patients beyond the role of the anaesthetist. The newly developed drugs have clear benefits to those surgeons who use local infiltration; the catheters and new delivery systems can be utilised by the surgeon to assist in postoperative analgesia. Current research which will dictate the future remains exciting with the development of drugs which have more rapid onset of action, formulations providing extended release of LA which could negate the need for catheters.

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Recent Advances in Surgery 36 once again provides the reader with a comprehensive up-to-date review of developments in the general field of surgical practice as well as in important specialised areas.The editors have carefully chosen topics in which important innovations have recently been incorporated into clinical usage. Each chapter is written by a recognised expert in the field and a relevant reference list is provided to assist with further reading.

The book is designed both for surgical trainees undertaking surgical examinations and established Consultants wishing to keep abreast of recent developments in surgical practice.



Irving Taylor MD ChM FRCS FMedSci FHEA is Professor of Surgery and Vice Dean (Professional Affairs) at University College London (UCL), London, UK. He has a particular clinical interest in surgical oncology and is past-President of the European Society of Surgical Oncology and the British Association of Surgical Oncology. He has been Professor and Head of Department of Surgery in Southampton and University College London (UCL) since 1981. He is an elected member of the Royal College of Surgeons of England. He is also case examiner for the fitness to practice directorate of the General Medical Council.



Colin D Johnson MChir FRCS is Reader in Surgery in the University of Southampton and Honorary Consultant Surgeon at University Hospital Southampton, Southampton, UK. He specialises in the treatment of pancreatic disease. He has been an editor of the British Journal of Surgery; and since 2009, he has been editor-in-chief of the Annals of the Royal College of Surgeons of England. He has also been an examiner for the final Fellowship of the Royal College of Surgeons (FRCS) (intercollegiate examination) since 2006.

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